DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region g1553d

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6005

July 25, 2001

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Mr. Ronald McCartney
President
Black Tiger Co. Inc.
1301 Bremen Avenue
Egg Harbor City, NJ 08215

File # 01-NWJ-31

Dear Mr. McCartney,

We inspected your firm, located at 1301 Bremen Avenue in Egg Harbor city, New Jersey, from June 25 through June 27, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your Marlin, Shad, Bluefish, Wahoo, vacuum packaged smoked fish and pasteurized crabmeat products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations included the following:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for the primary processing of Bluefish and Shad or for the secondary processing of Marlin, Shad and Wahoo to control the food safety hazard of histamine formation which is inherent in these products if not controlled. The lack of having written HACCP plans was previously brought to your attention during your firms last inspection dated June 18, 1999. Your written response to this observation dated June 21, 1999 stated your firm was "...currently reviewing our seafood HACCP plan..." and "All histamine and clostridium botulinum hazard seafood will be included."

Additionally, the HACCP plans in place and currently used by your firm for other products were not signed or dated.

2. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control histamine formation when your procedure for monitoring adequacy of ice and internal temperatures of Mackerel, Tuna, Bluefish and Mahi-Mahi were not followed on several dates between May 9, 2001 through June 20, 2001.

   Additionally, your firm's HACCP plan listed 45° as the temperature for implementation of corrective actions to control histamine formation. Please be advised that this temperature is inadequate for the proper control of histamine formation.

3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not monitor or record receiving or transit temperatures for your vacuum packaged smoked fish and pasteurized crabmeat products to control Clostridium Botulinum as stipulated in your HACCP plan for these products.

   This observation is a repeat observation and was included in the September 9, 1999 Untitled Letter to your firm. Your response to this observation dated October 21, 1999, in part stated, "All temperatures are taken on histamine and Clostridium Botulinum seafood upon receiving and recorded."

   Additionally, your response further stated that your firm's cooler "…is set to alarm at 38°F." and "Any corrective action that is taken is also recorded." However, our investigation revealed that the cooler was set to alarm at 50°F.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of monitoring records or other useful information that would assist us in evaluating your corrections. If you can not complete all corrections before you respond, we expect that you will explain

the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the act, the seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attn: Joseph F. McGinnis R.Ph, Compliance Officer, at the address and telephone number listed above.

Sincerely,

Edward H. Wilkens, for-
Douglas I. Ellsworth
District Director
New Jersey District